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| 10/551,738 | 02/07/2006 | Nikolay Khanzhin | 429-US-PCT | 4289 |
| 45821 | 7590 | 05/30/2008 | | |
| LUNDBECK RESEARCH USA, INC. ATTENTION: STEPHEN G. KALINCHAK, LEGAL 215 COLLEGE ROAD PARAMUS, NJ 07652 | | | EXAMINER CHU, YONG LIANG | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1626 | |
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| | | | 05/30/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/551,738

Applicant(s)

KHANZHIN ET AL.

Examiner

YONG CHU

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 5, 7-9, 11, 13, 14, 16, 19, 20 and 24-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 10, 12, 15, 17, 18 and 21-23 is/are rejected.
- 7) ☒ Claim(s) 1-4, 6, 10, 12, 15, 17-18, and 21-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/29/2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-37 are pending in the instant application.

Information Disclosure Statement

Applicants' Information Disclosure Statement, filed 09/29/2005 has been considered. Please refer to Applicant's copy of the PTO-1449 submitted herewith.

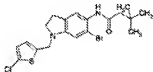
Priority

This application is a 371 of PCT/DK04/00283 filed on 04/23/2004, claims the benefit of U.S. Provisional Patent application No. 60/465,387 filed 04/25/2003, and the benefit of foreign priority of Denmark Patent Application No. PA200300631 filed 04/25/2003.

Response to Restriction/Election

Applicant's election with traverse of Group I (i.e. claims 1-23) and the elected

species of compound



as Example 6b in the Specification on

page 94 in the reply filed 03/03/2008 is acknowledged. Applicant traverses the restriction requirement on the ground that the Examiner has made no showing that prosecuting the claims of the invention in one application would be burdensome. Applicant's argument has been fully considered, but is found not persuasive. It is because that Groups I-II are classified in various subclasses of classes 514, 546, 548, and 549, and claim different inventions in category, which requires searching at different

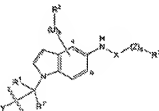
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criteria at different commercial database. It would be burden for the Examiner if the application were not restricted. Therefore, the restriction requirement is maintained.

Status of the Claims

Elected and Examined Subject Matter

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



A compound of the Formula (I) according to claim 1,

wherein:

R¹ and **R^{1'}** are hydrogen;

R² is hydrogen; **R³** is C₁₋₆alkyl or Ar-C₁₋₆alkyl;

Y is  or , wherein **W** is -S, **a** is 1, **f** is 0, and **R⁵** is halogen;

X is -CO;

q and **s** are 0; and a pharmaceutical composition comprising the compound thereof.

As a result of the election and the corresponding scope of the invention identified supra, claims 5, 7-9, 11, 13-14, 16, 19-20, and the remaining subject matter of claims 1-4, 6, 10, 12, 15, 17-18, and 21-23 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds and compositions contain varying functional groups which are chemically recognized to

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differ in structure, function, and reactivity. The scope of the invention is set in considering the elected species and the preferred embodiments. In addition, a reference, which anticipates one group, would not render obvious the other.

Therefore, claims 1-4, 6, 10, 12, 15, 17-18, and 21-23 will be examined on the merits.

Claim Rejections - 35 USC § 103(a)

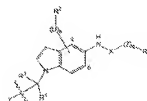
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6, 10, 12, 15, 17-18, and 21-23 are rejected under 35 U.S.C. 103 (a) as unpatentable over *U.S. Patent No. 7,084,176* by Morie et al. ("the '176 patent").



Applicants' claims relate to a compound of the Formula (I)

according to claim 1, wherein:

R¹ and **R^{1'}** are hydrogen;

R² is hydrogen; **R³** is C₁₋₆alkyl or Ar-C₁₋₆alkyl;

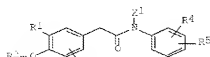
Y is  or , wherein **W** is -S, **a** is 1, **f** is 0, and **R⁵** is halogen;

X is -CO;

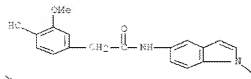
q and **s** are 0; and a pharmaceutical composition comprising the compound thereof.

Determination of the scope and content of the prior art (MPEP §2141.01)

The '176 patent discloses a compound of general formula



and a specific compound 244



(CH₃)₃CF₃ (CAS RN 478402-83-4) in Table 31,

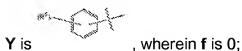
column 79, which is related to the instantly claimed scope of invention, wherein **R¹** and

R^{1'} are hydrogen;

R² is hydrogen; **R³** is Ar-C₁₋₆alkyl, **Ar** is a phenyl, substituted independently with one or more substituents as hydroxyl, or C₁₋₆alkyloxy according to instant specification at page

60;

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X is -CO; q and s are 0. This compound is used as a pharmaceutical agent.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the '176 patent and the instantly claimed inventions is that the prior art teaches the Compound 244 having "-(CH₂)₃-" linker between the indole ring and Y, but does not teach a compound having "-(CH₂)-" linker between the indole ring and Y.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The instantly claimed invention would have been obvious over the '176 patent, because one skilled in the art would have been motivated to prepare a homolog of a compound having "-(CH₂)-" linker between the indole ring and Y in view of the prior teaching of the compound having "-(CH₂)₃-" linker between the indole ring and Y, with the expectation of obtaining compounds which could be used in the related compounds or composition for pharmaceutical utility. To those skilled in the chemical art, one homologue (i.e. -(CH₂)₃- vs. -(CH₂)-) is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members, In re Wilder, 563 F.2d 457, 195USPQ 426 (CCPA 1977), and MPEP§2144.09. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. pharmacological

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use). Therefore, the instantly claimed compounds would have been suggested to one skilled in the art.

Claim Objection

Claims 1-4, 6, 10, 12, 15, 17-18, and 21-23 are objected to for containing elected and non-elected subject matter. The elected subject matter has been identified supra.

Conclusion

- Claims 1-4, 6, 10, 12, 15, 17-18, and 21-23 are objected to.
- Claims 1-4, 6, 10, 12, 15, 17-18, and 21-23 are rejected.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu, Ph.D./
Patent Examiner
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